PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference 664814	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/016128	29.10.2004	30.10.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant
KYOCERA CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

   ☒ paid additional fees

   ☐ paid additional fees under protest

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

Invention 1: Claims 1 and 17
Invention 2: Claims 2-4
Invention 3: Claims 5-11, 18-20, and part of claim 14
Invention 4: Claims 12, 13, 15, 16, and part of claim 14

Document 1 below describes a zirconia sintered body for a medical material having as its main ingredient zirconia stabilized by Y_2O_3 (Claim 1). Document 1 states that this sintered body contains SiO_2 and Al_2O_3 (Claims 1 and 3), and that the average crystal particle diameter is 0.5 μm or less (Claim 4).

Document 2 below describes an abrasion-resistant alumina ceramic containing ZrO_2 powder that contains Y_2O_3 and has an average particle diameter of 0.5 μm, Al_2O_3 powder, and a sintering auxiliary (Example 1, Test Sample 13).

Document 3 below describes a zirconia sintered body containing zirconia crystal particles with yittria in solid solution, and alumina (Examples). Document 3 states that the average particle diameter of the zirconia particles is 0.3 μm (page 4, Table 1), and this zirconia sintered body can be used as a bone head member in artificial joints and the like (Par. No. 0023).

As shown in these descriptions, the use of the composite ceramic specified in claim 1 of this application as a biomaterial is a publicly known technical matter, and this authority does not find a technical relationship that includes the same or corresponding "special technical feature" between Invention 1 and Inventions 2-4 above.

Because this authority does not find a technical relationship that includes the same or corresponding "special technical feature" among each of Inventions 2-4, Inventions 1-4 above cannot be considered to be a single group of inventions so related as to form a common single general inventive concept. Thus, this authority finds that the inventions of claims 1-20 of this application include 4 groups of inventions.

Document 1: JP 2000-191372 A (NGK Spark Plug Co., Ltd.) 11 July 2000
Document 2: JP 09-221354 A (Nikkato Corp.) 26 August 1997
Document 3: JP 2003-040673 A (Kyocera Corp.) 13 February 2003

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☒ all parts

   ☐ the parts relating to claims Nos. _____

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Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2-16, 18-20	YES
	Claims	1, 17	NO
Inventive step (IS)	Claims	19	YES
	Claims	1-18, 20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 2000-191372 A (NGK Spark Plug Co., Ltd.) 11 July 2000
Document 2: JP 09-221354 A (Nikkato Corp.) 26 August 1997
Document 3: JP 2003-040673 A (Kyocera Corp.) 13 February 2003
Document 4: JP 03-151978 A (Kyocera Corp.) 28 June 1991
Document 5: JP 06-172026 A (Matsushita Electric Works, Ltd.) 21 June 1994
Document 6: JP 60-204666 A (Aisin Seiki Co., Ltd.) 16 October 1985
Document 7: JP 05-294718 A (Mitsubishi Materials Corp.) 9 November 1993

Document 1 cited in the international search report describes a zirconia sintered body for a medical material having as its main ingredient zirconia stabilized by Y_2O_3 (Claim 1). Document 1 states that this sintered body contains SiO_2 and Al_2O_3 (Claims 1 and 3), and that the average crystal particle diameter is 0.5 μm or less (Claim 4).

Document 2 describes a abrasion-resistant alumina ceramic containing ZrO_2 powder that contains Y_2O_3 and has an average particle diameter of 0.5 μm, Al_2O_3 powder, and a sintering auxiliary (Example 1, Test Sample 13).

Document 3 describes a zirconia sintered body containing zirconia crystal particles with yittria in solid solution, and alumina (Examples). Document 3 states that the average particle diameter of the zirconia particles is 0.3 μm (page 4, Table 1), and this zirconia sintered body can be used as a bone head member in artificial joints and the like (Par. No. 0023). In addition, document 3 describes performing hot isostatic press (HIP) sintering at 1200 to 1600°C after sintering at 1350 to 1650°C (Par. Nos. 0010 and 0011).

Document 4 describes a ceramics for prosthesis of the body containing Al_2O_3 and ZrO_2 as constituent ingredients, and it states the strength and toughness are excellent (page 3, lower left column, lines 14 to 18).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V.

Document 5 describes a zirconia composite ceramic sintered body having a metallic phase wherein the second phase comprises Mo, W, and the like (Claim 1, Par. No. 0013), and it states that the ceramic sintered body preferably has a ceramic phase comprising Al_2O_3 (Par. No. 0014), and the ceramic sintered body obtained thereby has high strength and high toughness (Par. No. 0007). Furthermore, the Examples describe a ceramic sintered body formed from the material containing partially stabilized Zirconia powder having a particle size of 0.3 μm, Al_2O_3 particles, and Mo particles (page 13, Example 16).

Document 6 describes an aluminum oxide-based ceramic material comprising a mixed powder containing 0.5 to 1 wt% magnesium oxide, 0.1 to 3 wt% titanium oxide, 0.1 to 0.2 wt% silicon oxide, 8 to 15 wt% zirconium oxide partially stabilized by yittrium oxide, and aluminum oxide, and the average particle size of the mixed powder is 1 μm or less (Claim 1). Document 6 also states that hardness is improved and strength is increased in this ceramic material (page 1, right column, lines 14 to 16).

Document 7 describes an aluminum oxide-zirconium oxide based sintered ceramic with excellent toughness characterized by the fact that the main component of aluminum oxide comprises primarily the long growing crystals in the structure (Claim 1). Document 7 also states that because the main component of aluminum oxide comprises primarily the long growing crystals in the structure, it can be also combined with SrO and the like or SiO_2, and the like (Par. No. 0005). Furthermore, the Examples show sintered ceramics containing SrO, ZrO_2, and Al_2O_3 (page 4, Type 9).

○Claims 1 and 17

Documents 1-3 describe the inventions of the above claims, and therefore these inventions lack novelty and an inventive step with respect to documents 1-3.

○Claims 2-4

Documents 1-7 do not describe the inventions of the above claims, and therefore these inventions are novel.

When we compare the invention described in document 5 with the inventions of the claims of this application, the invention described in document 5 does not describe the use of the ceramic sintered body as a biological member, and in that respect they differ.

However, as described in documents 1-4 above, the use of a ceramic containing both alumina and zirconia as a biological member is conventional practice, and it is a publicly known matter that in so doing properties such as high levels of hardness and toughness are required (document 4). Therefore, this authority finds that persons skilled in the art can easily use the ceramic sintered body described in document 5 above that has a high level of hardness and toughness as a biological member.

Moreover, this authority finds that the effect provided thereby is not particularly outstanding.

Therefore, the inventions of claims 2-4 lack an inventive step with respect to documents 1-5.

Supplemental Box

Continuation of: Box V.

○Claims 5-11

Documents 1-7 do not describe the inventions of the above claims, and therefore these inventions are novel.

When we compare the invention described in document 6 with the inventions of the above claims of this application, document 6 does not describe that (A) the mean particle diameter of the zirconia crystal phase is 0.5 μm or less, and (B) that the ceramic material is used as a biological member, and in that respect they differ.

These differences are considered below.

With respect to (A), document 1 states that when the average crystal particle diameter in the zirconia crystal phase is 0.5 μm or less, phase transition of the sintered body is inhibited. (Par. No. 0014), and due to the inhibition of phase transition, the decrease in mechanical strength is inhibited (Par. No. 0010). This authority finds that based on the description in document 1, persons skilled in the art can easily optimize the powder particle diameter and sintering conditions in the invention described in document 6 so that the average particle diameter in the zirconia crystal phase will be 0.5 μm or less with the expectation of obtaining a similar effect.

With respect to (B), as described in documents 1-4, the use of a ceramic containing both alumina and zirconia as a biological member is commonly practiced, and it is a publicly known matter that in so doing properties such as high levels of hardness and toughness are required (document 4). Therefore, this authority finds that persons skilled in the art can easily use the ceramic member described in document 6 above that has a high level of hardness and toughness as a biological member.

Furthermore, this authority finds that persons skilled in the art can optimize the content of the various ingredients in the mix in document 6 near the values described in document 6 as needed in accordance with the purpose.

Moreover, this authority finds that the present invention does not provide any particularly outstanding effect that cannot be predicted from the descriptions in the above documents.

Therefore, the inventions of claims 5-11 lack an inventive step with respect to documents 1-4 and 6 above.

Supplemental Box

Continuation of: Box V.

○Claims 12-16

Documents 1-7 above do not describe the inventions of the above claims, and therefore these inventions are novel.

When we compare the invention described in document 7 with the inventions of the above claims of this application, document 7 does not describe that (A) the mean particle diameter of the zirconia crystal phase is 0.5 μm or less, and (B) that the ceramic material is used as a biological member, and in that respect they differ.

These differences are considered below.

With respect to (A), document 1 states that when the average crystal particle diameter in the zirconia crystal phase is 0.5 μm or less, phase transition of the sintered body is inhibited. (Par. No. 0014), and due to the inhibition of phase transition, the decrease in mechanical strength is inhibited (Par. No. 0010). This authority finds that based on the description in document 1, persons skilled in the art can easily optimize the powder particle diameter and sintering conditions in the invention described in document 7 so that the average particle diameter in the zirconia crystal phase will be 0.5 μm or less with the expectation of obtaining a similar effect.

With respect to (B), as described in documents 1-4, the use of a ceramic containing both alumina and zirconia as a biological member is commonly practiced, and it is a publicly known matter that in so doing properties such as high levels of hardness and toughness are required (document 4). Therefore, this authority finds that persons skilled in the art can easily use the sintering ceramic described in document 7 above that has superior toughness as a biological member.

The other differences have been discussed above.

Moreover, this authority finds that the present invention does not provide any particularly outstanding effect that cannot be predicted from the above documents.

Therefore, the inventions of claims 12-16 lack an inventive step with respect to documents 1-4, 6 and 7 above.

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Supplemental Box

Continuation of: Box V.

○Claims 18 and 20

Documents 1-7 above do not describe the inventions of the above claims of this application, and therefore these inventions are novel.

As described in document 3 above, baking a ceramic material at 1300 to 1500°C and then treating it by HIP at a lower temperature is a publicly known method, and this authority finds that persons skilled in the art can easily adopt this method in the invention described in document 6 above.

Moreover, this authority finds that no particularly outstanding effect is provided thereby.

The other differences have been discussed above.

Therefore, the inventions of claims 18 and 20 lack an inventive step with respect to documents 1-7 above.

○Claim 19

Documents 1-7 above neither describe nor suggest the invention of the above claim of this application, and therefore invention is novel and involves an inventive step with respect to documents 1-7.